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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/227,954	1-11-99	KI	

EXAMINER

HM12/1102

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ART UNIT	PAPER NUMBER
	7

DATE MAILED: 11/02/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☐ Claim(s) 34-59 is/are pending in the application.

Of the above, claim(s) 57-58 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 34-56, 59 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

1. Part III: Detailed Office Action

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647 of Group 1640, Technology Center 1600.

2. Formal Matters:

Some of the claims appear to rely on the use of a novel deposit, but applicants have not provided all of the required averments for deposited material (See MPEP Chapter 2300), and are thus, non-enabling for such. Contrary to applicant's statement at page 5 of the election/ amendment, a copy of the contract was not attached to this communication.

3. Restriction Requirement:

3a. Newly submitted claim 57 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

It is pointed out that although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for multiple/different products, restriction is deemed to be proper because the products appear to constitute patentably distinct inventions. Furthermore, the product of this claims, which presently appears to be indescribable as to whether it is a chemical compound or biological product whose make-up is not set forth, is directed to a product that appears to be structurally, physically, and functionally distinct from the protein product of the elected groups. The invention of claim 57 is also structurally, physically, and functionally distinct from the products of Groups I, III--V. Furthermore, this products are not required for each of the other products of the different groups, nor is this product required for used in each of the method of Groups I, and VI---X.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 57 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3b. Applicant's election with traverse of Group II, now claims 35-56, 58-59 (see the above comments for claim 57) in Paper No. 4 of 2/00 is acknowledged. The traversal is on the ground(s) that even where two patentably distinct invention are present, restriction is not proper if a serious burden can not be shown; that a search for the polypeptides would provide useful information for the other groups, and that many prior to biological products also disclose polynucleotides and antibodies to constitute overlapping subject matter. This is not found persuasive because most contrary to application's position, there would in fact be a serious burden on the examiner to both search and examine each of the various patentably distinct groups. While it is the case that there is overlap, "overlap" is not a proper basis for holding the restriction in error, and the patent literature and data base searches are not co-extensive for the search and examination of each of the groups. It is true that sometime certain art disclose multiple products, but this is not conclusively the case.

There the requirement is still deemed proper and is therefore made FINAL.

4. Objections and 35 USC 112 Rejections and 101 Rejections:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38, 45-46, 55 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38, 55 and any other similar claims or claims that depend for these are indefinite for being broader than the claim from which it depends because claim 37 refers to an encoded sequence of 2-92, but claim 38 requires an encoded sequence of 1-92.

Claims 45-46 are also indefinite because they appear to be duplicates of claims 37-38 respectively despite slight differences in the wording [see MPEP 706.03(k)].

Claims 35(b) at parts I, ii, and iii and claims 47(b) at parts I, ii and iii are indefinite in the use of "at least" because this fails to recite an upper limit, for which the specification has also not enabled (see below).

Furthermore part b(iii) of each of claims 35 and 47 are also indefinite in the recitation of 5% because the specification does not teach a specific method for determining such. The Algorithm used and the specific parameters of this percent are not defined in the specification. It is not clear of this refers to or encompass the non-coding regions and if provisions were made for gaps, and the introns and exons.

5. Claims 44 and 54 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A recovery step or purification step critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The presence of such a step is necessary to ensure that the preamble requirement for method of producing the polypeptide is achieved. Amending the claims to recite such would obviate this rejection.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35 [parts b(I)--->b(iii)], 35d. rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a reasonable number of modifications by way of insertions, deletions or substitutions in the nucleotide sequence for the encoded protein, does not reasonably provide enablement for: a) the upper limit of "at least one or more deletions, substitutions or insertions; b) nor for the enablement for 5% for the various modifications; c) nor the any variants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use with a reasonable expectation of success, the invention commensurate in scope with these claims.

For example, it is not clear if the deletion or inserted base would result in a frame-shift such that a different amino acid sequence results. And it is not clear if this resulting sequence will possess the desired activity. The nature and kind of base that can be inserted or deleted with a reasonable expectation of success has not been enabled. Nor has applicants shown that there is an established and reproducible assay of record for biological activity of the encoded protein. In fact the claims do not recite a specific biological activity, except for claims 44 and 54, but this does not appear to be sufficiently specific for a biological activity.

The maximum number of base substitutions for the protein would be expected to dramatically alter the physical and functional properties of the protein. Thus, in the absence of structure/function studies, the skilled artisan would be faced with undue experimentation. This undue experimentation results from the fact that the specification has not provided sufficient examples or guidance to direct the artisan to the appropriate regions where such varied modifications can be made. This is also complicated by the fact that this is a very small protein.

Even though the specification has recited general procedures and prior art citations for methods of making the various modifications, variants, and percent changes, these also do not serve as sufficient nor specific enablement based on all the reasons discussed above. Even if the claimed polynucleotide did not define such in terms of the encoded amino acid sequence, but rather contemplated the use of the DNA as hybridization probes, the scope of portions of these claims is so great that it would be expected that this would prevent selective or specific hybridization.

7. Prior Art Rejections:

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 35-56, 59 are rejected under 35 U.S.C. 102(a or b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hitomi (D49548 or D49549) or Hillier et al (R02722 or R02721).

Each of the prior art disclose nucleotide sequences which are 100% identical over the entire nucleic acid sequence, or 100% identical to the claimed encoded amino acid sequence (see the sequence alignment). The description for these sequences in the prior art states that it encodes for a protein, although the protein is referred to by a name that is different from the protein of the instant invention. Based on this sequence identity and the open-ended language of the claims, and the limitation for "at least", the prior art appears to anticipate the claims. Although the prior art protein and the claimed proteins are referred to by different names, the fact that the sequences are identical is what is controlling for establishing obviousness. Furthermore, any subsequent characterization of a prior art protein, which includes naming the protein or identifying biological activities and cleaving the protein to obtain non-specific fragments appear to represent further

characterization of a prior art protein (In re Swinehart, 169 USPQ 226). Although some of the claims are drafted in product-by-process form, the protein product appears to be the same irrespective of the process by which it is prepared, which is the controlling basis of this alternative 102/103 rejection (In re Brown, 173 USPQ 685). However, in the event the claims are not anticipated by the prior art, at the time of the invention it would have been prima facie obvious to use skills well known in the art to mutate or cleave the protein's sequence of the prior art in order to obtain polypeptides that possess the characteristics that meet the claim limitations. Thus, the burden is upon applicants to establish a patentable difference (In re Best 195 USPQ 430).

9. Claims 35-56, 59 are rejected under 35 U.S.C. 103 as being obvious over Hitomi (D49548 or D49549) or Hillier et al (R02722 or R02721) in view of Liao et al or Hara et al.

In addition to the teachings above, it is pointed out that although each of the primary references to Hitomi and each of Hillier et al do not refer to the protein by a particular name and the claims do not refer to the protein by a particular name, the fact that the nucleotide sequence and amino acid sequence are the same ensures that the prior art protein is the same as the claimed protein, despite differences in what the protein is referred to as. Not taught by the primary references is a method of using the nucleic acid to clone and expression of the encoded protein. At the time of the invention, it would have been prima facie obvious to follow the procedures of either of Liao et al or Hara et al, which teach the cloning and expression of other chemokines, to clone and express the encoded protein of the primary reference for the express purpose of obtaining another structurally and functionally related chemokine that could be used therapeutically or diagnostically, particularly since it is well known in the art that most of these small chemokines (C-C and the C-X-C) possess 50% or greater sequence identity, and the same or overlapping biological activity.

10. Copies of any prior being relied upon are not being provided herein, because such copies can be obtained from the parent application.

11. Advisory Information:

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to **Garnette D. Draper, Art Unit 1647, whose telephone number is (703) 308-4232.** Examiner Draper can normally be reached Monday through Friday, 9:30 A.M. to 6:00 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.

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GROUP 1800